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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,797	12/29/2000	Laure Dumoutier	LUD-5543.3 CONT.	5783

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EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/01/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/751,797

Applicant(s)

DUMOUTIER ET AL.

Examiner

Amy M. DeCloux

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7,8,10,11,14-16,18,19 and 50 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1,3,4,7,8,10,11,14-16,18,19 and 50 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 16 April 2001 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III, claims 1, 3-4, 7-8, 10-11, 14-16 and 18-19, in Paper No. 18, filed 4-17-02, is acknowledged. The traversal is on the ground(s) that Groups I and III should not be restricted because though the examiner has alleged unique biochemical and structural characteristics, the only difference is that their sequences are different and that SEQ ID NO:7 was used to isolate SEQ ID NO24. This is not found persuasive because though the examiner agrees with applicant that the two sequences share structural characteristics, said sequences are not identical and therefore they are not structurally identical. It is also noted that the sequences of Group I are murine while those of Group III are human. However, upon reconsideration, the examiner has agreed to join Groups I and II and to examine newly added claim 50.

2. The requirement is still deemed proper and is therefore made FINAL.

Drawings

3. The corrected or substitute drawings were received on 4-16-01, and have been approved by the draftsman. It is noted by the examiner that there is only one figure, yet said figure is labeled 1/17 at the top.

Specification

4. The disclosure is objected to because of the following informalities:

A) Page 12, line 1, discloses that SEQ ID NO:7 is 1121 bases long, when the paper copy of the SEQ ID NO:7 indicates said sequence is 1119 bases long.

B) Page 32, line 6, there is a space between the word "STAT1 and "c". *comma*

C) Page 32, line 20, there is a space between "m" and "uteins".

D) Page 33, line 6, there is a "/" after "muteins"; perhaps a period was intended.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claims 1, 3-4, 8, 10-11, 14-16, 18-19 and 50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for an isolated nucleic acid molecule which encodes a T cell inducible factor which activates STAT 3, wherein said isolated nucleic acid molecule consists of SEQ ID NO: 7, SEQ ID NO:8, SEQ ID NO:24 and SEQ ID NO:25, a vector thereof and a host cell thereof, does not reasonably provide enablement for any nucleic acid molecule which encodes a T cell inducible factor, a vector thereof, and a recombinant cell thereof, the complementary sequence of which hybridizes under stringent conditions to at least one of SEQ ID NO: 7, SEQ ID NO:8, SEQ ID NO:24 and SEQ ID NO:25.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims are drawn to an isolated nucleic acid molecule which encodes a T cell inducible factor which activates STAT 3, the complementary sequence of which hybridizes under stringent conditions to at least one of SEQ ID NO: 7, SEQ ID NO:8, SEQ ID NO:24 and SEQ ID NO:25, a vector thereof, and a host cell thereof.

Applicants have not disclosed an isolated nucleic acid molecule which encodes a T cell inducible factor which activates STAT 3, the complementary sequence of which hybridizes under stringent conditions to at least one of SEQ ID NO: 7, SEQ ID NO:8, SEQ ID NO:24 and SEQ ID NO:25, a vector thereof, and a host cell thereof, as recited in the instant claims, other than the nucleic acid molecules consisting of SEQ ID NO: 7, SEQ ID NO:8, SEQ ID NO:24 and SEQ ID NO:25, a vector thereof, and a host cell thereof. Neither have Applicants disclosed the structural basis for activation of STAT 3 by the T cell derived inducible factor encoded by the nucleic acids consisting of cDNA and genomic sequences of TIF.

By reciting hybridization terminology in the instant claims, said nucleic acid molecule can also encompass an indeterminate number and combination of nucleic acid substitutions in SEQ ID NO: 7, SEQ ID NO:8, SEQ ID NO:24 and SEQ ID NO:25 by an indefinite number of nucleic acid molecules capable of hybridizing even under stringent hybridization conditions, to a nucleic acid of cDNA and genomic sequences of TIF.

Predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar functions and properties requires a knowledge of, and guidance with regard to which amino acids in the sequence, if any, are tolerant of modification and which are conserved or less tolerant to modification, and detailed knowledge of the ways in which the product's structure relates to its functional usefulness. However, the problem of predicting functional aspects of the product from mere sequence data of a single nucleic acid sequence and what changes can be tolerated is complex and well outside the realm of routine experimentation, as evidenced by Doerks (1998) (TIG 14(6):248-250, see entire article).

This unpredictability is evidenced by applicant's own specification where it is disclosed on pages 12-14 that the induction by IL-9 of murine TIF beta, which has high homology to murine TIF alpha (and therefore hybridizes to murine TIFalpha under stringent conditions) is

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much lower than the expression of TIF alpha . Clearly nucleic acid molecules that hybridize under stringent conditions do not necessarily share common functions.

Neither the specification nor the prior art provides a structural basis for the recited activity of the encoded protein. Without such guidance, predicting which of the nucleic acids that hybridizes to at least one of SEQ ID NO: 7, SEQ ID NO:8, SEQ ID NO:24 and SEQ ID NO:25, and which possesses one of the claimed biological activities of being a T cell inducible factor which activates STAT 3, (other than an isolated nucleic acid molecule consisting of SEQ ID NO: 7, SEQ ID NO:8, SEQ ID NO:24 and SEQ ID NO:25), is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *Amgen, Inc. v. Chugai Pharmaceutical Co. Ltd.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991) at 18 USPQ2d 1026-1027 and *Ex parte Forman*, 230 USPQ 546 (BPAI 1986). *In re Fisher*, 166 USPQ 19 24 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Therefore, there is no evidence of record to show that one skilled in the art would be able to practice the invention as claimed without an undue amount of experimentation.

7. Claims 1, 3-4, 8, 10-11, 14-16, 18-19 and 50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of ordinary skill in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to an isolated nucleic acid molecule which encodes a T cell inducible factor which activates STAT 3 , the complementary sequence of which hybridizes under stringent conditions to at least one of SEQ ID NO: 7, SEQ ID NO:8, SEQ ID NO:24 and SEQ ID NO:25 , a vector thereof, and a host cell thereof.

By reciting hybridization terminology in the instant claims, said nucleic acid molecule can also encompass an indeterminate number and combination of nucleic acid substitutions in SEQ ID NO: 7, SEQ ID NO:8, SEQ ID NO:24 and SEQ ID NO:25 by an indefinite number of nucleic acid molecules capable of hybridizing even under stringent hybridization conditions, to a nucleic acid of cDNA and genomic sequences of TIF.

Applicants have not disclosed an isolated nucleic acid molecule which encodes a T cell inducible factor which activates STAT 3 , other than the nucleic acid molecules consisting of SEQ ID NO: 7, SEQ ID NO:8, SEQ ID NO:24 and SEQ ID NO:25, the invention encompassing any other nucleic acid which encodes a T cell inducible factor which activates STAT 3, the complementary sequence of which hybridizes under stringent conditions to at least one of SEQ ID NO: 7, SEQ ID NO:8, SEQ ID NO:24 and SEQ ID NO:25 , a vector thereof, and a host cell thereof , as recited in the instant claims. Neither have Applicants disclosed the structural basis for activation of STAT 3 by the T cell derived inducible factor encoded by the nucleic acids consisting of cDNA and genomic sequences of TIF. Since neither the specification nor the prior art provides a structural basis for the recited activity of the encoded protein, one of skill could not determine if one was in possession of a hybridizing nucleic acid molecule which encodes a T cell inducible factor which activates STAT 3 , other than a nucleic

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acid molecule consisting of SEQ ID NO: 7, SEQ ID NO:8, SEQ ID NO:24 and SEQ ID NO:25, without further description from the specification. Therefore the invention of the instant claims is not adequately described. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.)

It is noted that the instant specification discloses on page 29 that there is no disclosed limitation on the species from which the recited nucleic acid molecule originates, the complement of which hybridizes under stringent conditions to at least one of SEQ ID NO: 7, SEQ ID NO:8, SEQ ID NO:24 and SEQ ID NO:25, and therefore is not adequately described, *see University of California v. Eli Lilly and Co.* 43 USPQ2d 1398.

8. Claims 1, 3-4, 8, 10-11, 14-16, 18-19 and 50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to an isolated nucleic acid molecule which encodes a T cell inducible factor which activates STAT 3, the complementary sequence of which hybridizes under stringent conditions to at least one of SEQ ID NO: 7, SEQ ID NO:8, SEQ ID NO:24 and SEQ ID NO:25, a vector thereof, and a host cell thereof.

The instant claims are not supported by the specification or by the claims as originally filed. There is no support in the specification or claims as originally filed for the recitation of an isolated nucleic acid molecule which encodes a T cell inducible factor “which activates STAT 3”, the complementary sequence of which hybridizes under stringent conditions to at least one of SEQ ID NO: 7, SEQ ID NO:8, SEQ ID NO:24 and SEQ ID NO:25, a vector thereof, and a host cell thereof.

There is no written description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes **new matter**.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention

Claims 1, 3-4, 7-8, 10-11, 14-16, 18-19 and 50 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

A) Claims 1, 3-4, 8, 10-11, 14-16, 18-19 and 50 are indefinite in the recitation of “stringent conditions”. The term is defined in the specification only in exemplary form, and it is

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therefore unclear under which conditions the Applicants intend the claimed polynucleotide sequences to hybridize. This rejection could be overcome by listing the conditions disclosed on page 29, into the claim.

B) Claim 7 is indefinite in the recitation of "the protein encoded by the isolated nucleic acid of claim 1" because said protein lacks antecedent basis.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1, 3-4, 7-8, 10-11, 14-16, 18-19 and 50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 12 and 14 of U.S. Patent No. 6,331,613. Although the conflicting claims are not identical, they are not patentably distinct from each other because the isolated nucleic acid molecule, the complementary sequence of which hybridizes under stringent conditions to at least one of SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:24 or SEQ ID NO:25, a vector thereof, and a recombinant cell thereof, recited in the instant claims, encompass an isolated nucleic acid molecule having the nucleotide sequence of SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:24 or SEQ ID NO:25, a vector thereof, and a recombinant cell thereof, as recited in claims 1-10, 12 and 14 of U.S. Patent No. 6,331,613.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

July 1, 2002

Amy DeCloux, PhD,
Patent Examiner, Group 1640,

Amy DeCloux
7-1-02